

Dimension Vista® CSAE Flex® reagent cartridge
Special 510(k) Premarket Notification

510(k) Summary of Safety and Effectiveness
Dimension Vista® CSAE Flex® reagent cartridge

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

AUG - 5 2008

The assigned 510(k) number is: K081992

1. Submitter's Contact Information and Date of Preparation

Submitter's Contact Information: Siemens Healthcare Diagnostics Inc.
P.O. Box 6101
Newark, DE 19714-6601
Attn: Yuk-Ting Lewis
Tel: 302-631-7626

Date of Preparation: July 7, 2008

2. Proprietary Device Name / FDA Classification Name

Dimension Vista® CSAE Flex® reagent cartridge / Cyclosporine test system

3. Identification of the Predicate Device

Dimension® CSAE Flex® reagent cartridge, K052017

4. Device Description

The Dimension Vista® CSAE Flex® reagent cartridge is a pre-packaged in-vitro diagnostic test method (assay) that is specifically designed to be used on the Dimension Vista® Integrated system, a floor model, fully automated microprocessor-controlled, integrated instrument system. The Dimension Vista® system was previously cleared with seven associated test methods (K051087). This Special 510(k) is submitted for a packaging modification to the Dimension® Cyclosporine Extended Range (CSAE) Flex® reagent cartridge (K052017), an in-vitro diagnostic device that has been cleared under the 510(k) process for use on Dimension® clinical chemistry systems. The packaging change is to allow use on the Dimension Vista® system. The modifications also include a change in method parameters (sample size and reagent volume) but the final concentration of sample/reagent ratio in test milieu remains the same.

The reagents contained in the Dimension Vista® CSAE Flex® reagent cartridges are the same as those contained in the Dimension® CSAE Flex® reagent cartridges manufactured for the Dimension® clinical chemistry systems, another family of Siemens analyzers. The packaging modification does not affect the intended use of the devices, nor does it alter the fundamental scientific technology of the device.

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The CSAE method uses an immunoassay technique in which free and CSA bound antibody-enzyme species are separated using magnetic particles. The CSAE Flex® reagent cartridge contains a pretreatment reagent, β -galactosidase-CSA antibody conjugate, CSA immobilized on chromium dioxide particles, chlorophenol red β -d-galactopyranoside (CPRG) substrate, and diluent to hydrate the tablets. To perform the CSAE assay, a sample cup containing the whole blood sample to be analyzed and a CSAE Flex® reagent cartridge are placed appropriately on the Dimension Vista® system. The Dimension Vista® system mixes and lyses the whole blood sample. The lysed sample is then mixed with the antibody conjugate reagent. The CSA present in the sample is bound by the CSA antibody conjugate reagent. Magnetic particles coated with cyclosporine A are added to bind free (unbound) antibody-enzyme conjugate. The reaction mixture is then separated magnetically. Following separation, the supernatant containing the CSA antibody-enzyme complex is transferred to a cuvette and mixed with the substrate. β -galactosidase catalyzes the hydrolysis of CPRG (chlorophenol red β -d-galactopyranoside) to produce CPR (chlorophenol red) that absorbs light maximally at 577nm. The change in absorbance at 577nm due to the formation of CPR is directly proportional to the amount of CSA in the patient's sample and is measured using a bichromatic (577, 700nm) rate technique.

5. Device Intended Use

The CSAE method is an in vitro diagnostic test for the quantitative measurement of cyclosporine A (CSA) in human whole blood on the Dimension Vista® system. Measurements of CSA are used as an aid in the management of heart, liver and kidney transplant patients.

6. Summary of the devices technological characteristics

The Dimension Vista® CSAE Flex is substantially equivalent to other cyclosporine test systems, such as the Dimension® CSAE Flex® reagent cartridge (K052017). A comparison of features is provided.

Feature	Modified Device: Dimension Vista® CSAE Flex® reagent cartridge	Predicate Device: Dimension® CSAE Flex® reagent cartridge
Reagents	Prepackaged, 12 well plastic Flex® reagent cartridges	Prepackaged, 8 well plastic Flex® reagent cartridges
Intended Use	The CSAE method is an in vitro diagnostic test for the quantitative measurement of cyclosporine A (CSA) in human whole blood on the Dimension Vista® system. Measurements of CSA are used as an aid in the management of heart, liver and kidney transplant patients.	The CSAE method is an in vitro diagnostic test for the quantitative measurement of cyclosporine A (CSA) in human whole blood on the Dimension® clinical chemistry system. Measurements of CSA are used as an aid in the management of heart, liver and kidney transplant patients.

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Feature	Modified Device: Dimension Vista® CSAE Flex® reagent cartridge	Predicate Device: Dimension® CSAE Flex® reagent cartridge
Final concentration of sample/reagent ratio in test milieu	Same concentration as the predicate device	As described in K052017
Reagent form	Same liquids and tablets	Liquids and tablets
# of chrome tablets	2	3
Total # of tests in each Flex® cartridge	30	20
Calibration	30 days	30 days
Sample Type	Whole blood	Whole blood
Analytical Measurement Range	350 – 2000 ng/mL	350 – 2000 ng/mL
Sample Size	1.12 µL	3 µL
Measurement	Bichromatic endpoint @ 577 and 700 nm	Bichromatic endpoint @ 577 and 700 nm

7. Method comparison to the predicate

A split sample method comparison study was conducted on the Dimension Vista® CSAE Flex vs. the Dimension® CSAE Flex using one hundred and sixteen (116) transplant samples. The data was analyzed using least squares linear regression and produced the following regression statistics:

Slope	0.92
Intercept	37.9 ng/mL
r	0.990
n	116

8. Conclusion

The proposed Dimension Vista® CSAE method is substantially equivalent to the legally marketed device, the Dimension® CSAE method in design, principle, and performance. They have the same intended use and indications for use. Comparative testing also demonstrates substantially equivalent performance.



SEP 2 - 2008

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Healthcare Diagnostics Inc.
c/o Ms. Yuk-Ting Lewis
Regulatory Affairs and Compliance Manager
P.O. Box 6101, Mailbox 514
Newark, DE 19714-6101

Re: k081992

Trade/Device Name: Dimension Vista CSAE Flex Regent Cartridge, Model k4108
Regulation Number: 21 CFR 862.1235
Regulation Name: Cyclosporine Test System.
Regulatory Class: Class II
Product Code: MKW
Dated: July 11, 2008
Received: July 14, 2008

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K081992

Device Name: Dimension Vista® CSAE Flex® reagent cartridge

Indications For Use:

The CSAE method is an in vitro diagnostic test for the quantitative measurement of cyclosporine A (CSA) in human whole blood on the Dimension Vista® system. Measurements of CSA are used as an aid in the management of heart, liver and kidney transplant patients.

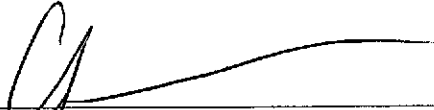
Prescription Use x
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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